UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,307	04/20/2004	Michael B. Zemel	31894-202097	2558

26694 7590 06/21/2006

VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20045-9998

EXAMINER	
WEBMAN, EDWARD J	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/827,307	ZEMEL ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-14, 16, 17, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metz et al (AJH 1:58-60 1988).

Metz et al teach a reduction in body fat content in rats consuming higher diets of calcium (abstract).

It would have been obvious to one of ordinary skill to formulate a high calcium diet for humans to achieve the beneficial effect of a reduction in body fat content in view of the Metz et al results.

As to the particular claimed dosage frequency, amount, and vehicle, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). One of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes.

Applicant argues that Metz et al teaches both calcium and sodium ions. However, applicants do not exclude sodium. Applicant argues unexpected results. However, Metz et al, prior to applicant's effective date, disclose applicant's invention. Applicant argues extensive experimentation, however, applicants do not demonstrate that the dosages are critical or that the experimentation to determine them was not routine. Applicants object to the examiner taking notice regarding documentation. As to the statement that a

reduction in body fat content is a consequence of lipolysis of fat in adipocytes, the examiner cites US 6,716,810 column 17 lines 29-48, wherein the inventors refer to fat stores metabolized from peripheral adipose tissue by stimulation of lipolysis from adipocytes. As to the fact that the claimed foods are well known to contain calcium the examiner refers to Table 2 from the NIH fact sheet on calcium available on the internet.

Claims 1-8, 10-14, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner et al (Scand J Nutr 2/99 suppl 34 p. 45S).

Skinner et al teach that children's fat mass is moderated by dietary calcium (abstract).

It would have been obvious to one of ordinary skill to formulate a high calcium diet for children to achieve the beneficial effect of a reduction in body fat content in view of the Skinner et al.

As to the particular claimed dosage frequency, amount, and vehicle, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). One of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes.

Applicant argues that Skinner et al does not concern calcium alone nor did the study concern weight loss. However, regarding variants other than calcium leading to the results in Sinner et al, applicants do not exclude them. As to the claimed weight loss, such is claimed in the alternative. The rejection is directed to the claimed metabolic consumption of adipose tissue. However, even if

applicant limited the rejection to weight losee, the calculation of fat mass in Skinner et al is derived from the body mass index (BMI) of subjects, for which the correlation is significant. That is, decreases in fat mass correlate with a decrease in BMI. Applicant argues that Skinner et al was not directed to individuals regulating body weight. However, had Skinner et al been so directed, the results would have been more pronounced. Applicant argues unexpected results, however, the Skinner et al teaching is prior to applicant's effective date. Applicant also objects to the examiner's reliance on determining applicant's dosage by routine experimentation and the examiner's taking of official notice, however, the examiner's response to these objections is incorporated herein from the rejection over Metz et al *supra* as it relates to Skinner et al.

Claims 1-17, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summerbell et al (BMJ 317 1998 p. 1487-89).

Summerbell et al teach weight loss in obese patients on a diet comprising milk or yoghurt (abstract, p. 1488 under "milk only").

It would have been obvious to one of ordinary skill to formulate a high calcium diet for obese patients to achieve the beneficial effect of a reduction in body fat content in view of the Summerbell et al.

As to the particular claimed dosage frequency, amount, and vehicle, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). As to the calcium, it is well known, even to the layman, that dairy products contain calcium. One of ordinary skill will recognize

that reduction in body fat content is a consequence of lipolysis of fat in adipocytes.

Applicants argue that Summerbell et al teach away from a milk only diet, but rather teach diet rotation. However, that diet rotation would include the milk only diet or the theoretically superior milk plus diet. Applicants do not exclude diet rotation nor do they exclude a milk plus diet. Applicant also objects to the examiner's reliance on determining applicant's dosage by routine experimentation and the examiner's taking of official notice, however, the examiner's response to these objections is incorporated herein from the rejection over Metz et al *supra* as it relates to Summerbell et al.

Applicant's submissions discussed on pages 12-13 may demonstrate recognition by the public that the invention has the utility claimed. However, the issue at hand is non-obviousness.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0648. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500